

House Study Bill 46 - Introduced

HOUSE FILE _____
BY (PROPOSED COMMITTEE
ON COMMERCE BILL BY
CHAIRPERSON LUNDGREN)

A BILL FOR

1 An Act relating to price transparency and cost-sharing for
2 prescription drugs, and including applicability provisions.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 510D.1 Definitions.

2 As used in this chapter, unless the context otherwise
3 requires:

4 1. *"Commissioner"* means the commissioner of insurance.

5 2. *"Dispenser"* means the same as defined in 21 U.S.C.
6 §360eee(3).

7 3. *"Established name"* means the same as defined in 21 C.F.R.
8 299.4.

9 4. *"Health benefit plan"* means the same as defined in
10 514J.102.

11 5. *"Pharmaceutical drug manufacturer"* or *"manufacturer"* means
12 any person engaged in the business of producing, preparing,
13 converting, processing, packaging, labeling, or distributing
14 a prescription drug. *"Pharmaceutical drug manufacturer"* or
15 *"manufacturer"* does not include a wholesale distributor or a
16 dispenser.

17 6. *"Prescription drug"* means the same as defined in 21
18 U.S.C. §360eee(12).

19 7. *"Wholesale acquisition cost"* or *"cost"* means a
20 manufacturer's list price for a prescription drug for
21 wholesalers or direct purchasers in the United States, not
22 including prompt pay or other discounts, rebates, or reductions
23 in price, for the most recent month for which the information
24 is available, as reported in wholesale price guides or other
25 publications of drug or biological pricing data.

26 8. *"Wholesale distributor"* means the same as defined in 21
27 U.S.C. §360eee(29).

28 Sec. 2. NEW SECTION. 510D.2 Pharmaceutical drug
29 manufacturers — annual report.

30 Each manufacturer shall provide an annual report by
31 February 15 to the commissioner, in a format prescribed
32 by the commissioner, that contains the current wholesale
33 acquisition cost for each prescription drug manufactured by the
34 manufacturer that was sold to a person in this state in the
35 immediately preceding calendar year. Within thirty calendar

1 days of receipt, the commissioner shall publish the information
2 received by the commissioner on a publicly accessible internet
3 site.

4 Sec. 3. NEW SECTION. 510D.3 **Wholesale acquisition cost**
5 **increase — report.**

6 1. If a prescription drug sold to a person in this state
7 has a wholesale acquisition cost of one hundred dollars or more
8 for a thirty-day supply and the cost increases forty percent
9 or more over the three preceding consecutive calendar years,
10 or increases fifteen percent or more in the preceding calendar
11 year, the manufacturer of the prescription drug shall file a
12 report with the commissioner within thirty calendar days of the
13 date on which the forty percent or the fifteen percent increase
14 in the cost occurs. The report shall be in the form and manner
15 prescribed by the commissioner and shall include all of the
16 following information:

17 *a.* The established name of the prescription drug.

18 *b.* All brand names, generic names, proprietary names, and
19 nonproprietary names for the prescription drug, as applicable.

20 *c.* The aggregate manufacturer-level research and development
21 costs related to the prescription drug for the most recent
22 calendar year for which third-party independent audit data for
23 manufacturer-level research and development costs is available.

24 *d.* All established names, brand names, generic names,
25 proprietary names, and nonproprietary names for each
26 prescription drug manufactured by the manufacturer that
27 received approval from the United States food and drug
28 administration in the immediately preceding three consecutive
29 calendar years.

30 *e.* All established names, brand names, generic names,
31 proprietary names, and nonproprietary names for each
32 prescription drug manufactured by the manufacturer for which
33 a patent or exclusivity expired in the immediately preceding
34 three consecutive calendar years.

35 *f.* A statement detailing the factor or factors that played

1 any role in the increase in cost of the prescription drug
2 and an explanation for the factor or factors' impact on the
3 increase in cost of the prescription drug.

4 *g.* The aggregate manufacturer-level direct and
5 administrative costs related to marketing and advertising of
6 the prescription drug for the immediately preceding calendar
7 year.

8 2. All information and data a manufacturer submits to the
9 commissioner must be consistent in detail and quality with the
10 information and data submitted in the manufacturer's annual
11 report filed with the United States securities and exchange
12 commission on form 10-k.

13 3. *a.* Information provided by a pharmaceutical drug
14 manufacturer to the commissioner pursuant to this section
15 that may reveal any of the following as related to a specific
16 prescription drug or class of prescription drugs shall
17 be considered a confidential record, and be recognized
18 and protected as a trade secret pursuant to section 22.7,
19 subsection 3:

20 (1) The amount the manufacturer charges a specific health
21 carrier, specific pharmacy benefit manager, or a specific
22 dispenser.

23 (2) The dollar value of the rebates the manufacturer
24 provides a specific health carrier, specific pharmacy benefit
25 manager, or a specific dispenser.

26 (3) The identity of a specific health carrier, specific
27 pharmacy benefit manager, or a specific dispenser.

28 *b.* Within sixty calendar days of receipt of the information
29 pursuant to this section, the commissioner shall publish all
30 nonconfidential information received by the commissioner on the
31 same publicly accessible internet site referenced in section
32 510D.2.

33 **Sec. 4. NEW SECTION. 510D.4 Rules.**

34 The commissioner shall adopt rules pursuant to chapter 17A
35 as necessary to administer this chapter.

1 Sec. 5. NEW SECTION. 510D.5 **Summary enforcement.**

2 1. Upon a determination by the commissioner that a
3 manufacturer or manufacturer's agent has engaged, is engaging,
4 or is about to engage in any act or practice in violation of
5 this chapter, a rule adopted by the commissioner, or an order
6 issued by the commissioner under this chapter, the commissioner
7 may do any of the following:

8 *a.* Issue a summary order, including a brief statement
9 of findings of fact and conclusions of law, and direct the
10 manufacturer or manufacturer's agent to cease and desist from
11 engaging in the act or practice.

12 *b.* Take other affirmative action that in the judgment of
13 the commissioner is necessary to ensure that the manufacturer
14 or manufacturer's agent comply with this chapter, and rules
15 adopted and orders issued by the commissioner under this
16 chapter.

17 2. *a.* A manufacturer or manufacturer's agent that has
18 been issued a summary order under this section may contest
19 the order by filing a request for a contested case proceeding
20 and hearing as provided in chapter 17A, and in accordance
21 with rules adopted by the commissioner. The manufacturer or
22 manufacturer's agent shall have at least thirty calendar days
23 from the date that the summary order is issued to file the
24 request. If a hearing is not timely requested, the summary
25 order shall be final by operation of law.

26 *b.* Section 17A.18A shall not apply to a summary order issued
27 under this section.

28 *c.* A summary order issued pursuant to this section shall
29 remain effective from the date of issuance unless overturned by
30 a final decision of a presiding officer or by a final judgment
31 of the court.

32 3. A manufacturer or manufacturer's agent violating
33 a summary order issued under this section shall be deemed
34 in contempt of that order. The commissioner may petition
35 the district court to enforce the order as certified by

1 the commissioner. The district court shall adjudge the
2 manufacturer or manufacturer's agent in contempt of the order
3 if the court finds after hearing that the manufacturer or
4 manufacturer's agent is not in compliance with the order. The
5 court may assess a civil penalty against the manufacturer or
6 manufacturer's agent of not more than one thousand dollars
7 per day for each day that the manufacturer or manufacturer's
8 agent is in violation of the order. A civil penalty collected
9 pursuant to this section shall be deposited as provided in
10 section 505.7. The court may issue further orders as the court
11 deems appropriate.

12 Sec. 6. NEW SECTION. 510E.1 Definitions.

13 As used in this chapter unless the context otherwise
14 requires:

15 1. "*Commissioner*" means the commissioner of insurance.

16 2. "*Covered person*" means the same as defined in section
17 514J.102.

18 3. "*Dispenser*" means the same as defined in 21 U.S.C.
19 §360eee(3).

20 4. "*Health benefit plan*" means the same as defined in
21 section 514J.102.

22 5. "*Health care professional*" means the same as defined in
23 section 514J.102.

24 6. "*Health carrier*" means the same as defined in section
25 514J.102.

26 7. "*Pharmaceutical drug manufacturer*" or "*manufacturer*" means
27 any person engaged in the business of producing, preparing,
28 converting, processing, packaging, labeling, or distributing
29 a prescription drug. "*Pharmaceutical drug manufacturer*" or
30 "*manufacturer*" does not include a wholesale distributor or a
31 dispenser.

32 8. "*Prescription drug*" means the same as defined in 21
33 U.S.C. §360eee(12).

34 9. "*Prescription drug benefit*" means a health benefit plan
35 providing for third-party payment or prepayment of prescription

1 drugs.

2 10. "*Specialty drug*" means a prescription drug that a health
3 carrier has designated as a specialty drug and that has either
4 of the following characteristics:

5 a. The United States food and drug administration has
6 designated the prescription drug an orphan drug.

7 b. The manufacturer of the prescription drug, or the United
8 States food and drug administration, restricts distribution of
9 the prescription drug to a limited number of distributors.

10 11. "*Utilization review*" means the same as defined in
11 section 514F.7.

12 12. "*Utilization review organization*" means the same as
13 defined in section 514F.7.

14 Sec. 7. NEW SECTION. 510E.2 **Health carriers — annual**
15 **report.**

16 1. Each health carrier shall submit an annual report
17 by February 1 to the commissioner, in the form and manner
18 prescribed by the commissioner, that contains the following
19 information for the immediately preceding calendar year, across
20 all of the health carrier's health benefit plans that offer a
21 prescription drug benefit:

22 a. The brand name of the twenty-five prescription drugs most
23 frequently covered by the prescription drug benefits offered
24 by the health carrier.

25 b. The percent increase in annual spending by the health
26 carrier to provide all prescription drug benefits offered by
27 the health carrier.

28 c. The percent increase in premiums paid by covered persons
29 attributable to all prescription drug benefits offered by the
30 health carrier.

31 d. The percentage of specialty drugs included in all
32 prescription drug benefits offered by the health carrier that
33 are subject to utilization review conducted by a utilization
34 review organization.

35 e. The percent decrease in premiums paid by covered persons

1 attributable to specialty drugs that are subject to utilization
2 review conducted by a utilization review organization that
3 are included in all prescription drug benefits offered by the
4 health carrier.

5 2. Any information a health carrier provides to the
6 commissioner pursuant to subsection 1 that may reveal any of
7 the following shall be considered a confidential record, and be
8 recognized and protected as a trade secret pursuant to section
9 22.7, subsection 3:

10 a. The identity of a specific health benefit plan.

11 b. The identity of the specific price charged by a specific
12 manufacturer, pharmacy benefit manager, or dispenser for a
13 specific prescription drug or class of prescription drugs.

14 c. The dollar value of the rebates a specific manufacturer,
15 a specific pharmacy benefit manager, or a specific dispenser
16 provides to the health carrier.

17 3. Prior to May 1 of each calendar year, the commissioner
18 shall publish the nonconfidential data received by the
19 commissioner pursuant to this section on the same publicly
20 accessible internet site referenced in section 510D.2. The
21 data shall be aggregated from all annual reports submitted
22 pursuant to subsection 1, and the information shall be
23 made available to the public in a format that complies with
24 subsection 2.

25 Sec. 8. NEW SECTION. 510E.3 Rules.

26 The commissioner shall adopt rules pursuant to chapter 17A
27 as necessary to administer this chapter.

28 Sec. 9. NEW SECTION. 510E.4 Summary enforcement.

29 1. Upon a determination by the commissioner that a health
30 carrier or a health carrier's agent has engaged, is engaging,
31 or is about to engage in any act or practice in violation of
32 this chapter, a rule adopted by the commissioner, or an order
33 issued by the commissioner under this chapter, the commissioner
34 may do any of the following:

35 a. Issue a summary order, including a brief statement of

1 findings of fact and conclusions of law, and direct the health
2 carrier or health carrier's agent to cease and desist from
3 engaging in the act or practice.

4 *b.* Take other affirmative action that in the judgment
5 of the commissioner is necessary to ensure that the health
6 carrier or health carrier's agent comply with this chapter, and
7 rules adopted and orders issued by the commissioner under this
8 chapter.

9 2. *a.* A health carrier or health carrier's agent that has
10 been issued a summary order under this section may contest
11 the order by filing a request for a contested case proceeding
12 and hearing as provided in chapter 17A, and in accordance
13 with rules adopted by the commissioner. The health carrier
14 or health carrier's agent shall have at least thirty calendar
15 days from the date that the summary order is issued to file the
16 request. If a hearing is not timely requested, the summary
17 order shall be final by operation of law.

18 *b.* Section 17A.18A shall not apply to a summary order issued
19 under this section.

20 *c.* A summary order issued pursuant to this section shall
21 remain effective from the date of issuance unless overturned by
22 a final decision of a presiding officer or by a final judgment
23 of the court.

24 3. A health carrier or health carrier's agent violating
25 a summary order issued under this section shall be deemed
26 in contempt of that order. The commissioner may petition
27 the district court to enforce the order as certified by the
28 commissioner. The district court shall adjudge the health
29 carrier or health carrier's agent in contempt of the order if
30 the court finds after hearing that the health carrier or health
31 carrier's agent is not in compliance with the order. The court
32 may assess a civil penalty against the health carrier or health
33 carrier's agent of not more than one thousand dollars per
34 day for each day that the health carrier or health carrier's
35 agent is in violation of the order. A civil penalty collected

1 pursuant to this section shall be deposited as provided in
2 section 505.7. The court may issue further orders as the court
3 deems appropriate.

4 Sec. 10. NEW SECTION. 514M.1 Definitions.

5 1. "*Carrier*" means an entity subject to the insurance laws
6 and regulations of this state, or subject to the jurisdiction
7 of the commissioner, that offers at least one health plan in
8 this state.

9 2. "*Cost-sharing requirement*" means any copayment,
10 coinsurance, deductible, or other out-of-pocket expense
11 obligation required of or on behalf of an enrollee in order
12 for the enrollee to receive a specific health care service,
13 including a prescription drug, covered by the enrollee's health
14 plan.

15 3. "*Enrollee*" means an individual who is eligible to obtain
16 health care services under a health plan.

17 4. "*Health care services*" means an item or service for the
18 prevention, treatment, cure, or healing of an illness, injury,
19 or physical disability.

20 5. "*Health plan*" means a policy, contract, certificate, or
21 agreement offered or issued by a carrier to provide, deliver,
22 arrange for, pay for, or reimburse any of the costs of health
23 care services.

24 6. "*Interchangeable biological product*" means the same as
25 defined in section 155A.3.

26 7. "*Internal Revenue Code*" means the Internal Revenue Code
27 as defined in section 422.3.

28 8. "*Person*" means a natural person, corporation, mutual
29 company, unincorporated association, partnership, joint
30 venture, limited liability corporation, trust, estate,
31 foundation, not-for-profit organization, government or
32 governmental subdivision, or government or governmental agency.

33 9. "*Specialty drug*" means the same as defined in section
34 510E.1.

35 Sec. 11. NEW SECTION. 514M.2 Cost-sharing calculation.

1 1. A carrier shall include all cost-sharing amounts paid by
2 an enrollee, or need-based payments paid by another person on
3 behalf of the enrollee, as part of the carrier's calculation
4 of an enrollee's contribution to the enrollee's applicable
5 cost-sharing requirement. This requirement does not apply
6 to cost-sharing amounts paid by an enrollee, or by another
7 person on behalf of an enrollee, for a specialty drug or a
8 prescription drug for which a medically appropriate A-rated
9 generic equivalent or an interchangeable biological product is
10 available to the enrollee.

11 2. Subsection 1 shall not apply to a state-regulated
12 high-deductible health plan to the extent it results in the
13 plan's failure to qualify as a high-deductible health plan
14 pursuant to section 223 of the Internal Revenue Code.

15 3. If a provision of subsection 1 conflicts with a federal
16 law or regulation as applied to a specific carrier or to a
17 specific circumstance, the provision shall remain in full force
18 and effect for all carriers and in all circumstances in which
19 the federal conflict does not exist.

20 Sec. 12. NEW SECTION. 514M.3 **Applicability.**

21 This chapter applies to all health plans delivered, issued
22 for delivery, continued, or renewed in this state on or after
23 January 1, 2022.

24 Sec. 13. **RETROACTIVE APPLICABILITY.**

25 1. The section of this Act that requires a pharmaceutical
26 drug manufacturer to submit an annual report to the
27 commissioner containing the current wholesale acquisition cost
28 for each of the manufacturer's prescription drugs is applicable
29 to all manufacturers that manufactured any prescription drug
30 that is sold to a person in this state on or after January 1,
31 2021.

32 2. The section of this Act that requires a pharmaceutical
33 drug manufacturer to submit a report to the commissioner
34 containing information related to an increase in the wholesale
35 acquisition cost of a prescription drug manufactured by

1 the manufacturer is applicable to all manufacturers that
2 manufactured any prescription drug that is sold to a person in
3 this state on or after January 1, 2021.

4 3. The section of this Act that requires a health carrier
5 to submit an annual report to the commissioner related to all
6 of the health carrier's health benefit plans that offer a
7 prescription drug benefit is applicable to all health benefit
8 plans providing for third-party payment or prepayment of health
9 or medical expenses that provide a prescription drug benefit
10 that have been delivered, issued for delivery, continued, or
11 renewed in this state on or after January 1, 2021.

12 EXPLANATION

13 The inclusion of this explanation does not constitute agreement with
14 the explanation's substance by the members of the general assembly.

15 This bill relates to price transparency and cost-sharing for
16 prescription drugs.

17 The bill requires a manufacturer to file an annual report
18 with the commissioner of insurance (commissioner) that
19 discloses the wholesale acquisition cost for all prescription
20 drugs manufactured by the manufacturer that were sold to a
21 person in this state in the immediately preceding calendar
22 year. "Wholesale acquisition cost" or "cost" is defined in the
23 bill as the manufacturer's list price for a prescription drug
24 for wholesalers or direct purchasers in the United States, not
25 including prompt pay or other discounts, rebates, or reductions
26 in price, for the most recent month for which the information
27 is available, as reported in wholesale price guides or other
28 publications of drug or biological pricing data. Within 30
29 calendar days of receipt, the commissioner is required to
30 publish the information from the annual reports on a publicly
31 accessible internet site.

32 If a prescription drug sold to a person in this state
33 has a cost of \$100 or more for a 30-day supply and the cost
34 increases 40 percent or more over the three preceding calendar
35 years, or increases 15 percent or more in the preceding

1 calendar year, the manufacturer of the prescription drug must
2 file a report with the commissioner within 30 calendar days
3 of the date on which the 40 or 15 percent increase in cost
4 occurs. This requirement is applicable to all manufacturers
5 that manufactured prescription drugs that are sold to a
6 person in this state on or after January 1, 2021. The report
7 must include the information detailed in the bill. Certain
8 information provided by a manufacturer, as detailed in the
9 bill, is considered a confidential record and is required
10 to be protected as a trade secret. Within 60 calendar days
11 of receipt, the commissioner is required to publish the
12 nonconfidential information on the same publicly accessible
13 internet site on which the manufacturer's annual report
14 information is published.

15 The bill requires each health carrier to submit an annual
16 report by February 1 to the commissioner that contains
17 information as detailed in the bill across all of the health
18 carrier's health benefit plans. This requirement is applicable
19 to all health benefit plans providing for third-party payment
20 or prepayment of health or medical expenses that provide a
21 prescription drug benefit that have been delivered, issued
22 for delivery, continued, or renewed in this state on or after
23 January 1, 2021. "Health carrier" is defined in the bill as an
24 entity subject to the insurance laws and regulations of this
25 state, or subject to the jurisdiction of the commissioner,
26 including an insurance company offering sickness and accident
27 plans, a health maintenance organization, a nonprofit health
28 service corporation, a plan established pursuant to Code
29 chapter 509A for public employees, or any other entity
30 providing a plan of health insurance, health care benefits,
31 or health care services. Certain information provided by
32 a health carrier, as detailed in the bill, is considered a
33 confidential record and must be protected as a trade secret.
34 Prior to May 1 of each year, the commissioner must publish the
35 nonconfidential data received by the commissioner on the same

1 publicly accessible internet site on which the manufacturers'
2 information is published. The data must be aggregated from the
3 annual reports submitted by all health carriers.

4 The bill directs the commissioner to adopt rules as
5 necessary to administer the requirements outlined in the
6 bill. The bill details the commissioner's authority, and
7 the process to enforce that authority, for manufacturers',
8 manufacturers' agents', health carriers' or health carriers'
9 agents' violations of a provision of the bill, a rule adopted
10 by the commissioner, or of an order issued by the commissioner.

11 The bill also requires a carrier to include all cost-sharing
12 amounts paid by an enrollee of a health plan, or by another
13 person on behalf of an enrollee, as part of the carrier's
14 calculation of an enrollee's contribution to the enrollee's
15 applicable cost-sharing requirement. This does not
16 apply to cost-sharing incurred for a specialty drug or a
17 prescription drug for which an A-rated generic equivalent or an
18 interchangeable biological product is available. "Cost-sharing
19 requirement" is defined in the bill as any copayment,
20 coinsurance, deductible, or other out-of-pocket expense
21 obligation required of or on behalf of an enrollee in order
22 for the enrollee to receive a specific health care service,
23 including a prescription drug, covered by the enrollee's health
24 plan. This requirement applies to all health plans delivered,
25 issued for delivery, continued, or renewed in this state on
26 or after January 1, 2022. The bill excludes state-regulated
27 high-deductible health plans (HDHP) from the requirement if
28 it will result in the plan not qualifying as an HDHP under
29 section 223 of the Internal Revenue Code. The bill also
30 prohibits application of the requirement to a carrier or to a
31 circumstance in a manner that will conflict with a federal law
32 or a federal regulation.